748 ★ Presidential Poster of Distinction

SAFETY AND EFFICACY OF SOFOSBUVIR/VELPATASVIR IN PEDIATRIC PATIENTS 6 TO < 18 YEARS OLD WITH CHRONIC HEPATITIS C INFECTION

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Abstract Text

Background: Direct acting antiviral (DAA) regimens have been approved for teh treatment of HCV in adolescents aged 12 to <18 years, but for younger children, the standard of care is still pegylated-interferon plus ribavirin for up to 48 weeks. The current study evaluated the safety and efficacy of an all-oral DAA treatment with the pangenotypic regimen of sofosbuvir (SOF)/velpatasvir (VEL) in children 6 to <18 years old.

Methods: Patients aged 6 to <18 years old with chronic HCV of any genotype were enrolled into this open-label, ongoing study to receive the fixed dose combination SOF/VEL. Patients 6 to <12 years old received SOF/VEL 200 mg/50 mg and 12 to <18 years old received SOF/VEL 400mg/100mg once daily for 12 weeks. The key efficacy endpoint was SVR12. Safety was assessed by adverse events (AEs) and clinical/laboratory data. Intensive pharmacokinetic (PK) sampling on Day 7 in a subgroup of patients (N=17) of each age group was done to confirm the appropriateness of the chosen dose.

Results: A total of 102 patients 12 to <18 years old and 73 patients 6 to <12 years were enrolled and treated. The genotype distribution overall was 75% GT1, 5% GT2, 13% GT3, 3% GT4, 3% GT6; 51% were female, 80% white, 85% treatment naïve, and 91% vertically infected. Intensive PK confirmed that the doses selected were appropriate. The SVR12 rate among patients 12 to <18 years old was 95% (97 of 102) and among the 6 to <12 years old was 92% (67 of 73); one patient in each age group had virologic failure and the remaining 9 patients did not achieve SVR for non-virologic reasons such as lost to follow-up. Most AEs were mild or moderate in severity. In total, 5 subjects had a serious AE, none of which was attributed to treatment. Two patients discontinued treatment due to AEs; neither AE was considered treatment related. The most common AEs (>15% of patients) were headache, fatigue, and nausea in adolescents and vomiting, cough and headache in 6 to <12 year olds.

Conclusion: In patients 6 to <18 years old with chronic GT1, 2, 3, 4 or 6 HCV infection, treatment with SOF/VEL for 12 weeks resulted in ≥92% SVR12 rate. This pangenotypic regimen was well tolerated overall, supporting its potential as a treatment option for children 6 to 17 years of age. The study is ongoing in children aged 3 to <6 years old.

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